AAL
ACTIVE AND ASSISTED LIVING
PROGRAMME

AAL Guidelines

for Ethics, Data Privacy and Security

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Abstract

The AAL Guidelines for Ethical Excellence provide the AAL Community with a model that integrates general law compliance with an ethical dialogue. It also provides reflections on how to set up ethical excellence for solutions targeting active and heathy ageing through digital technologies.

Statement of originality

This document contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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INTRODUCTION AND SCOPE

What is the aim of these AAL Guidelines?

The main aim of this document is to provide the Active and Assisted Living (AAL) Community of stakeholders with guidelines for ethics, data privacy and security regarding digital solutions for the Active and Healthy Ageing (AHA) domain, fostering two main aspects:

- to be compliant with existing regulations, standards, etc.
- to aim for ethical excellence

Who are these Guidelines aimed at?

This document is designed for all researchers, developers, primary, secondary and tertiary end-users, policy makers, start-ups and enterprise innovators in the AAL domain. It can support the successful adoption and use of their solution by integrating an ethical and basic legal perspective right from the development stage of products and services.

Why are the Guidelines important?

As technology is rapidly progressing, very often the final users of AAL solutions face difficulties, such as lack of digital skills or a sense of rejection towards new technologies. This means that gaps in information and communication about their rights and privacy need to be thoroughly addressed, throughout the complete cycle of development, from ideation to market launch and use.

Human-machine interaction needs to be designed to respond to the highest ethical, legal and privacy/data management standards and requirements. This is essential to protect the older citizens, but also to guarantee the viability of the business solutions, ensuring they are legally compliant and realistically matching the European and national regulations.

However, besides this technological human-machine interaction ethics, there is also the need to anticipate the complex settings where the AAL products and services will be used, which involve stakeholders, as well as organisational and budgetary challenges that compose the broad AAL market.
The specificities of the main beneficiaries of the AAL solutions – the older adults – may include physical, mental and functional increasing impairment with age and thus also increasing risks of unacceptance, lack of adaptation or lack of access, among others.

This specific ethical challenge that AAL solutions face imply the need for a more robust method, including not only compliance with legal regulations, but also the search for excellence in ethics.

Ethical excellence is not a 'nice to have', but a '<u>must have</u>', not only for human and societal reasons, but also for success in the market.

Most of the AAL solutions are not purchased by the older adults themselves, but by the secondary users - all kinds of organisations in the regulated market, such as municipalities, health care and

social care organisations, and even informal caregivers. These buyers will be encouraged to buy a solution that is aiming for the highest standards.

Most stakeholders in the AAL Community are familiar with EU regulations applicable to AAL products and services, namely in the field of Active and Healthy Ageing. And several European Programmes (e.g. H2020, Eurostars) have adequate and solid guides for regulatory compliance, that project partners should follow and that can be easily accessed and used.

Through these guidelines, AAL goes one step further and demands more than just legal and ethical compliance, – it proposes **Ethical Excellence**, by fostering the implementation of the ethical dialogue and integrating relevant values in an iterative process of discussion. And applies this method not only during projects' lifetime but also for solutions already in the market.

Thus, these Guidelines intend to go beyond the (legal) state-of-the-art by providing the Community with a simple guide towards excellent ethical behaviour:

To do the right thing, at the right time, in the right way.

THE AAL MODEL FOR EXCELLENCE

Ethical excellence in all stages – conceptualisation &(co)creation; development& testing; market entry & scale-up - can leverage the trust of citizens and organisations, fostering the adoption of AAL solutions and services. To this aim, a two-fold complementary model of ethical excellence is proposed, that integrates compliance (left columns of the picture) with the ethical dialogue (right column of the picture); further details are in the next sections and in the graph below:

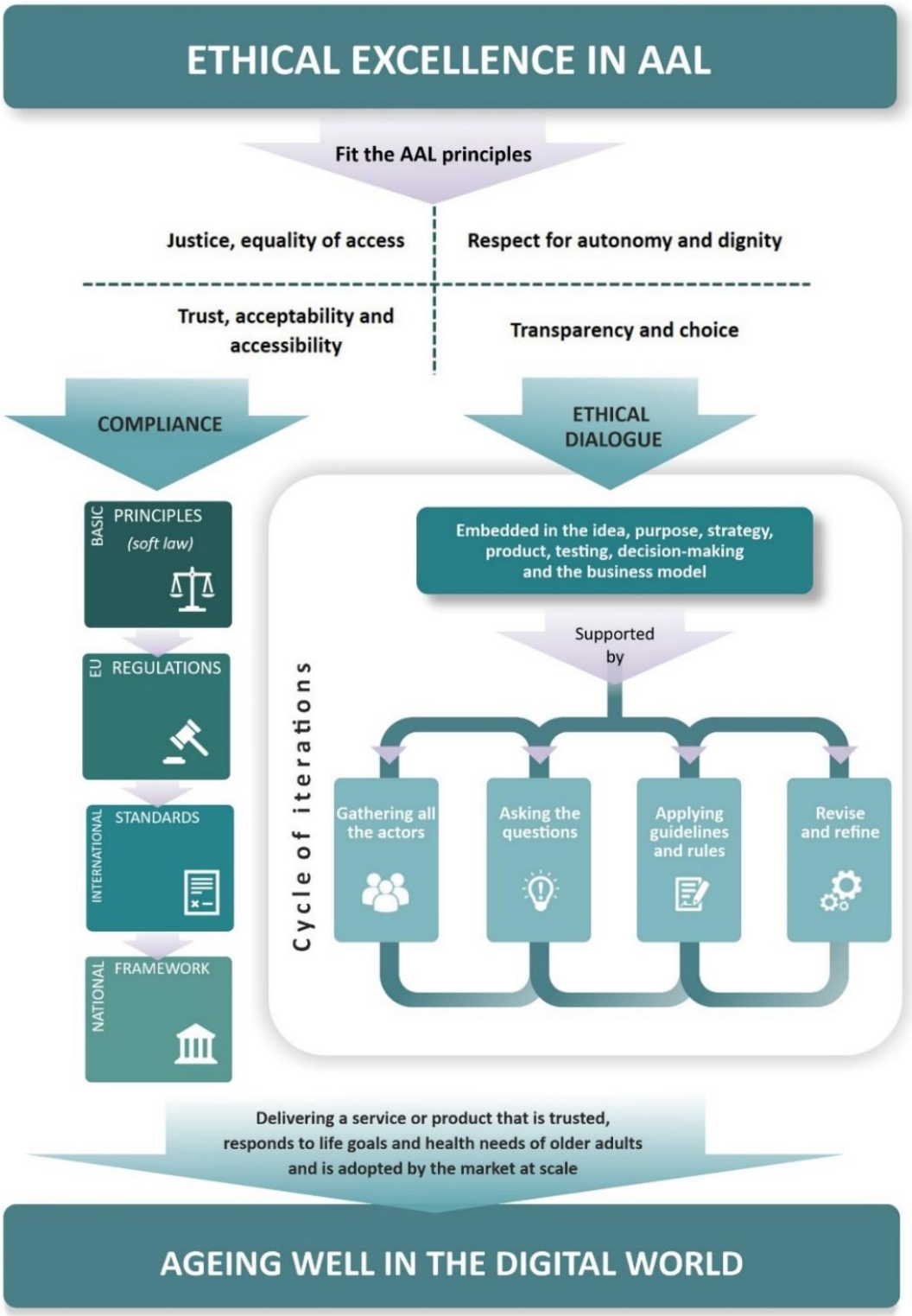
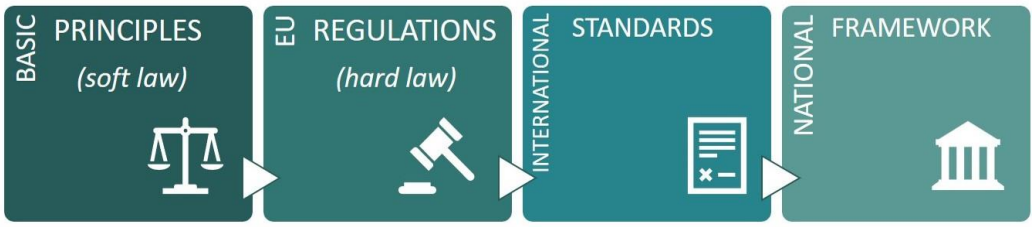


Figure 1 - The ethical excellence model

FRAMEWORK FOR COMPLIANCE



The framework for compliance in AAL comprises four steps:

Basic principles

Fundamental Ethical principles indicate that an intent to do good or provide help must always be the underlying motive for action. However, intent to do good is not sufficient. The potential for good must sufficiently outweigh the potential for harm.
This soft law concept includes a series of ethical codes of conduct, texts and principles to guide the protection and respect of the human rights and dignity of human beings, based on 4 principles (beneficence, non-maleficence, autonomy and justice).

EU Regulations

This area refers to a set of constructed legal directives and regulations to enforce the protection of any endeavor involving human beings (i.e. Convention of Oviedo) or the data privacy and security (i.e. GDPR General Data Protection Regulation).
The European Data Protection concern is not new, it is an ongoing reform process continuously adapting and based on 3 main principles:

- to build on the previous Data Protection Directives since 1995 (95/46/EC),
- to increase transparency and accountability of the data processing,
- to enhance the data protection rights of the individuals.

With the emerging digital age – e.g. big data, Internet of Things, automation/robotics, artificial intelligence, machine learning and blockchain – some very relevant legislation for AAL was approved, as the 2018 General Data Protection Regulation No. 679/2016 (GDPR) and the text currently under discussion: the new EU ePrivacy Regulation, supplementing GDPR for electronic communication of personal data.
These regulations aim at protecting the population and consumers from data collection, processing and data management procedures involving human data privacy and security.

This is particularly important for people in vulnerable situations, which can be the case of some older adults or people with disabilities. In the AHA domain, AAL has become expert in the Research & Development of new innovative solutions and their readiness for the market and, thus, gives high relevance to data protection regulations. Complying with these key requirements is a must!

GDPR: General Data Protection Regulation key points

The GDPR is a set of data protection rules for all organisations operating in the EU, wherever they are based or wherever their data processing activities are taking place. Stronger rules on data protection mean people have more control over their personal data, while businesses benefit from clear regulations for the market.
Personal data is any information that relates to an actual living individual (not legal entities). This includes, e.g.: name, surname, home address, e-mail or location data from the map on your mobile. Typically, this would be the case of the data that any organisation holds on employees, clients or suppliers.
The protection of personal data and its processing - e.g. through Apps, mobile data, payment transfers, ePlatforms, tracking or sensors for guidance, surveillance, domotics - are submitted to the GDPR and fundamental rights in the EU. If the data is anonymized and not traceable at any point in time, even with justifiable automated decision-making, the GDPR does not apply.
The GDPR is directly applicable in EU countries. The majority of EU Member States integrated its rules with their national laws, thus national or regional data protection authorities are increasingly applying the GDPR, and also issuing severe sanctions when it is not duly observed.

For additional information, this **Webinar** can provide some guidance.

International Standards

The European Union has established a system of standards and rules for bringing innovation, services and products safely to the market, in full respect of its citizens' rights and privacy. They directly apply to the functioning and general security measures of the product or service itself, such as the label "CE" or "ISO", but also concern the privacy and security of personal data.
There are some relevant standards to be considered for the AAL community:

- ISO TC314 | Ageing Committees - https://www.iso.org/committee/6810883.html
- ISO 82304-2 | Health and wellness apps - https://www.iso.org/standard/78182.html

As for CE marking (https://ec.europa.eu/growth/single-market/ce-marking_en), it applies to specific products, indicating that the manufacturer declares compliance of that product with the relevant European product safety legislation. It is, in principle, a self-certification process. Only for a few products it is required to have the product tested and certified by a Notified Body.

National framework and regional regulations

After ensuring that a product or service is complying with the different international regulations - and eventually adding value to it by conforming to standards or achieving the CE mark -, it is still necessary to ensure that it also obeys to the national or regional regulations of the countries where it will be used or commercialised.
For the development phase this usually implies the need to acquire ethical approval for studies; when going to the market it may be required to have specific authorisation from municipalities, regions or national agencies.

THE ETHICAL DIALOGUE

These AAL guidelines present a dedicated model that aims to support the Community in the implementation of an ethical dialogue regarding their AAL product or service and that can and should be used several times during the process from concept to (general) use:

Approach for guidance ethics:

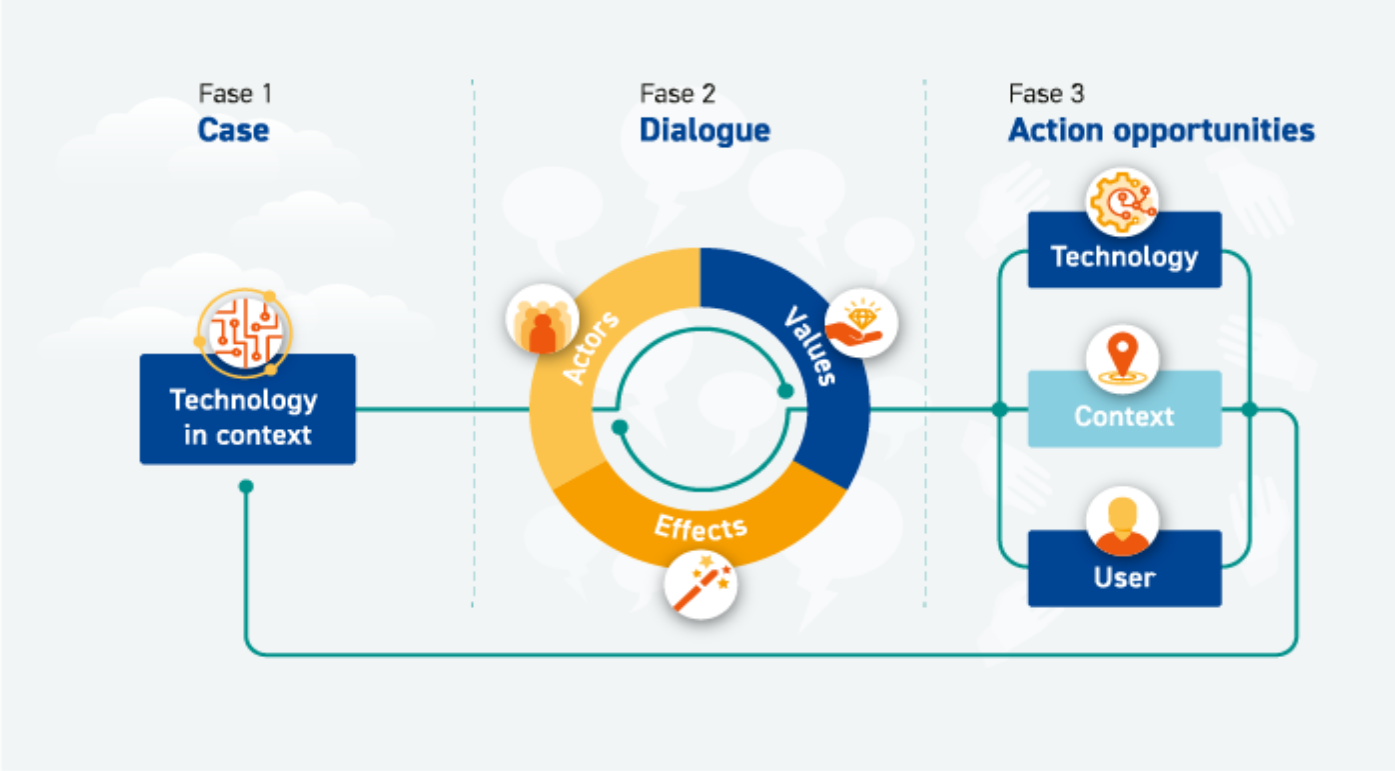


Figure 2 - The ethical dialogue

The model has three PHASES:

1) **Technology in context**

When starting a dialogue, be sure to have a good picture about the technology and the surrounding where it will be used. AAL solutions very often consist of a combination of different technologies and services (ICT and/or human). All these aspects can have their own ethical aspects, e.g. surveillance by sensors, GPS tracking, exchange of personal information etc. All these different aspects should be considered in the ethical dialogue about a solution.

2) **Dialogue**

In a dialogue it is important to have the (perspectives of) participants involved. Different actors have different expectations about the effects of the technology: positive and negative, personal and societal. The aim is to get all hopes and worries to the table. Behind the expectations of the effects are values: what values are important to the different stakeholders, from the AAL-perspective and how does the project connect to these values.
Solutions change in time, evolve and adapt in different situations.

3) Action opportunities

After drafting a clear view on the technology and context and on the main effects and values after a stakeholder dialogue, the main question is "What can we do to make it better?"

Actions to be taken in the last phase must include the following 3 main dimensions:

- Ethics by DESIGN (e.g. engineering, design)
- Ethics by CONTEXT (e.g. agreements, policy)
- Ethics by INDIVIDUAL (e.g. behaviour, awareness)

In the following sections, this model is tailored for AAL specificities.

THE MODEL: APPLY the ethical action dialogue to AAL

An ethical action dialogue is a new form to deal with ethics, as it is not just a dialogue, but also a call for action (innovation). It does not start top-down, but bottom-up.
With AAL solutions, there is often a specific focus on values connected to the protection of vulnerable people; therefore, it is necessary to be very familiar with the user's needs.

This dialogue shall be organised in the different stages of any development project:

- conceptualisation and (co) creation
- development& testing
- market entry & scale-up

In any phase, it is important to reflect on the values and effects of the service or product at stake and to find action possibilities to (ethically) improve it.

In every new phase, the needs for improvement that resulted from the previous stage are implemented and tested and a new dialogue emerges, also with potential new stakeholders.
E.g. in the conceptualization phase, there is the need for people who can conceptualize, who can understand what the effects are of an idea. In the market phase, there may be the need of people who understand business or marketing or safety measurements. Nevertheless, a multidisciplinary team from the very beginning is the optimal solution for having different emphasis at various stages.
The results of the different ethical action dialogues may be part of a future library of ethical actions, useful for potential benchmarking by the different projects and initiatives.
In the following pages, 3 tools will be provided to implement the model:

- FORM A – TECHNOLOGY IN CONTEXT
- FORM B – IMPLEMENTING THE DIALOGUE
- FORM C – DEFINING THE ACTIONS

By using and applying these 3 forms, the ethical dialogue is implemented, fulfilling legal compliance and driving to ETHICAL EXCELLENCE.

FORM A: TECHNOLOGY IN CONTEXT

1. Sketch the solution enabled by technology

In AAL, there are different kinds of solutions enabled by technologies in areas such as, health&care, living&building, safety&security. A useful taxonomy can be found here. For the dialogue it is important that all stakeholders understand what the solution is about.
Define and describe your solution here:

2. Sketch the context where the solution will be used.

What are the main characteristics of the target group, where do they live, how do they live, what interactions do they have? What organisations are involved?
E. g., older adults, at home, in residential units, cared for by professionals, neighbours, family, a lot of life experience, not that much life expectancy, not working, maybe volunteering, …
For the dialogue it is important that all stakeholders understand where and by whom the solution will be used (primary and secondary users).
Define and describe your context here:

Method: Invite a technological expert and/or an expert of the context. Let him/her/them inform the group. Only informational questions will be asked, opinions are for later in the process.

FORM B: IMPLEMENTING THE DIALOGUE

PARTICIPANTS

Invite relevant people for the ethical dialogue. This could be the developers of the solution, the users (clients), policymakers (in organisation or administration), care professionals, informal caregivers and/or others that have a role in the process or are influenced by the use of the

solution. It is important that some of the participants also have the power to bring improvements. If it is impossible to get all the right people around the table, try to ensure at least that all the perspectives are considered in the group.

EFFECTS

This is the start of the dialogue.

a) Ask the question: *what are the effects that could occur using this solution in this context?* Explain that these effects can be positive or negative. Be sure to have enough room for both of them. They might be direct or indirect, and try to gather effects for the different actors.

b) From the answers collected, try to focus on *what effects are most important, what are really the desired effects, what are the non-desirable effects, the ones to be avoided*.

VALUES

Connect your reflections to values.

a) Ask the question: *Which values played a role in the dialogue in the previous phases?* This can be asked directly to the group or a co-moderator could have noted the values and bring them into the dialogue at this new stage.

b) Ask the question: *Are the main AAL values well considered in this product/service?*

The question to be answered is what values are most important in this case, and how the AAL main principles presented below are addressed by the solution:

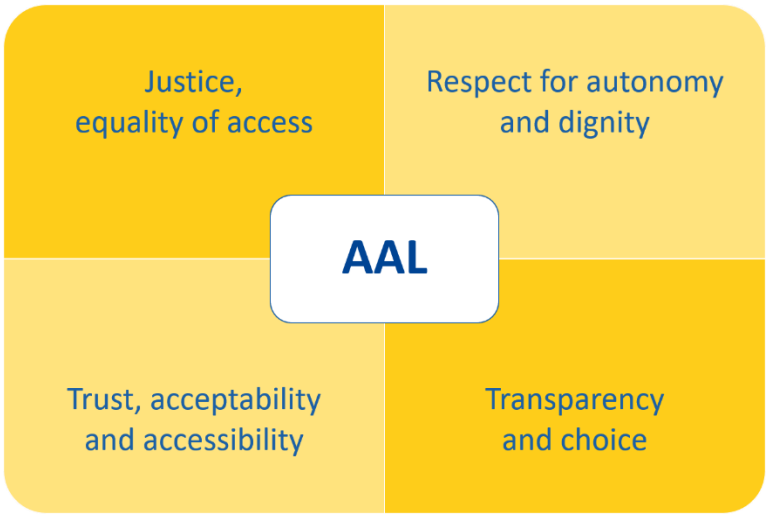


Figure 3 - The AAL principles

Method:

- Use a neutral moderator – even better if he/she is familiar with the method (and the context)
- This is not a discussion (who is right or wrong), it is a dialogue (exchanging of ideas and arguments): "we are trying to make something better, there are no winners or losers at the table, every input is important".
- Ensure a 'safe' environment (Chatham House rules[1])
- The goal of the dialogue must be made very clear to all participants, as well as the purpose - what will be done with the results.

[1] https://www.chathamhouse.org/chatham-house-rule#

FORM C: ACTION OPPORTUNITIES

Having completed the shared picture of the effects and the most important values, the last phase starts. How to make this solution have more positive and less negative effects, in accordance with the AAL values, supplemented by values of the participants. The actions shall be organised in 3 areas: the technology (ethics by design), the context and the behaviour of the individual.

ETHICS BY DESIGN (e.g. engineering, design)

a) *How can technology be improved* - which actions will you implement?

Examples: blurred camera's (privacy), anonymized data, data tuned on the user group, nice colours (attractiveness), washable (usability), universal design (easy to connect), accessibility, understandable information, a red button (when something goes wrong), etc.

ETHICS BY CONTEXT (e.g. agreements, policy)

b) *What can be improved in the AAL context* - which actions will you implement?

Examples: rules of use, agreements about who has access to data, and when, a helpdesk, technology innovation demands, standardisation, part of the payment protocol,

ETHICS BY INDIVIDUAL (e.g. behaviour, awareness)

c) *What can be improved for the users* - which actions will you implement?

People mostly have to learn how to use new technologies, at all different levels.
Examples: digital literacy, digital divide, ageing process, health professionals training to use the new product/service, communication about the (effects of) the new technology.

Method:

- This phase is mostly done in subgroups
- This is also a creative phase, so brainstorm is important
- Conceptualize and make it as concrete as possible
- Define what actions opportunities can become actions.
- If people around the table can do an action, ask them to.
- For the other actions: define a first step.

Practical examples – a use case

There are a lot of AAL projects. This is only an example to clarify what it could mean to use the ethical action method.

The case: 2PCS: Personal protecting and caring system

The 2PCS system is a mobile emergency – and location system, which was developed to answer the requirements of professional care and ensuring the independence of people in care. This solution enables use in various life and care phases, both in inpatient and outpatient care. The 2PCS system consists of several specially developed units, which are combined to form a holistic system.

The different 2PCs products/parts are:

- 2PCS SAFETY WATCH: a mobile alarm and location system
- 2PCS PERSONAL TRANSMITTER: a mobile alarm and location system
- 2PCS ANTENNA
- 2PCS SOFTWARE PLATFORM

The 2PCS software platform is part of the 2PCS system, a mobile call and location system. On this platform, emergencies and warnings which are triggered, for example, by the 2PCS safety watch or the 2PCS personal transmitter, are displayed or forwarded to compatible alarm systems.

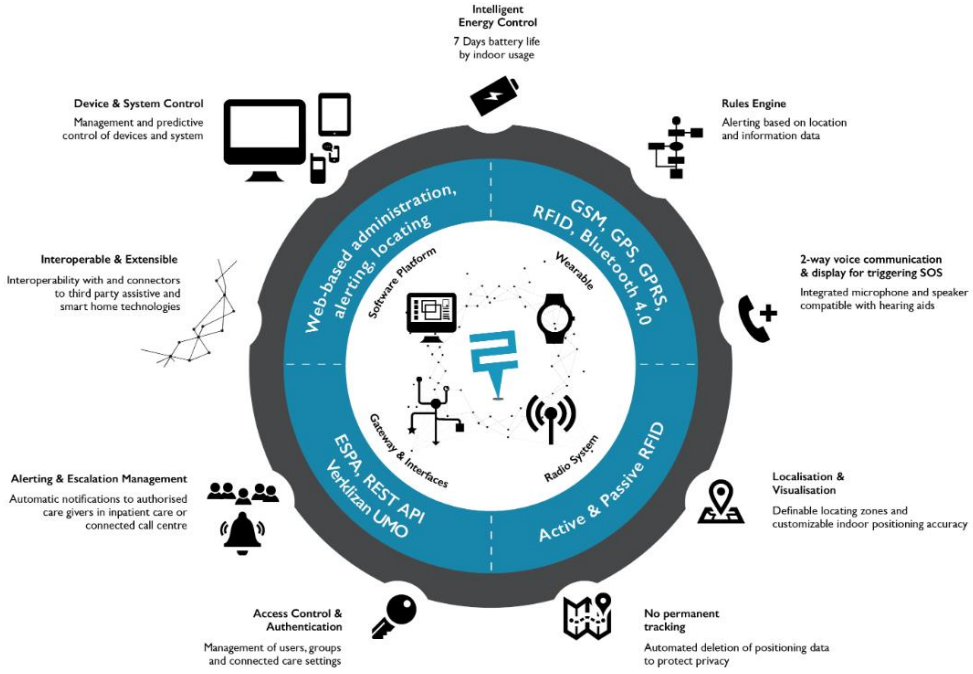


Figure 4 - P2CS architecture

The dialogue

Possible Actors in the dialogue: Older adults, care takers, family, designers, healthcare professionals, (call center workers), managers of care organizations, …

Possible effects and questions:

- People have to wear a device. Do they have to be trained?
- A call center function should be organized
- People feel more secure?
- People dare to go further away from their home?
- Who is getting a signal when something is wrong: family, care takers?
- How many 'false positives'? What are the effects: not listening anymore, panic?
- Who is going to pay for the device? And for the back-end?
- Who solves technological problems or malfunctions?
- What is the targeted market for this product?
- Are there standards to follow in this area?
- What effects can tracing have on privacy?
-

Values: Freedom, safety, closeness, independence, cost-efficiency, usability, beauty (design), … AAL values: Autonomy is enhanced, is it accessible though to those with lower incomes?

The ethical solutions

Ethics by design (e.g. technology, engineering, design)

- Making technology more reliable (how many missed emergencies, how many unnecessary?)
- Create a way to put off the device and/or to switch of certain functionalities, if wanted
- Can it be more beautifully designed, do people have choices of colours, aspect?
- Make it easily repairable
- Is tracking necessary?
- Where does the data go to, who is in control of that choice?
-

Ethics by context (e.g. agreements, policy)

- Define what people (health professionals, family) do when the alarm sounds (the protocol)
- Create a technical helpdesk? (how many: one per country, one per care company?)
- Who is going to pay for the device and for the system?
- Will it be mandatory?
-

Ethics by individual (e.g. behaviour, awareness)

- Create a program for users to learn about the device: the use, the effects
- Organise workflows of communication on use and problems of the device.